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August 6, 2004  
Submitted in Duplicate

Division of Documents Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Re: 2005 Program Priorities in the Center for Food  
Safety and Applied Nutrition  
[Docket No. 1998N-0359]

Dear Sir:

The International Bottled Water Association (IBWA) appreciates the opportunity to submit comments to the U.S. Food and Drug Administration (Agency) on the June 24, 2004, *Federal Register* notice requesting input for the establishment of program priorities in the Center for Food Safety and Applied Nutrition (CFSAN) for 2005.

IBWA is the authoritative source of information about all types of bottled waters. Founded in 1958, IBWA's membership includes U.S. and international bottlers, distributors and suppliers. The Association is committed to working with FDA, which regulates bottled water as a packaged food product, and state governments to set stringent bottled water standards for safe, high quality products bottled water products.

IBWA requests that the following items be placed on CFSAN's A list for Program Priorities for 2005: (1) finalization of a standard of quality for arsenic; and (2) cooperative development of strategies for reduction of security risks for bottled water. In addition, IBWA requests that revising the monitoring requirements for the nine contaminants for bottled water be included on CFSAN's B list for 2005. IBWA's detailed comments are as follows:

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1. Standard of Quality for Arsenic: IBWA has noted and supports FDA designating the development of a proposal to revise the bottled water quality standard for arsenic as an A level priority on the 2004 CFSAN Program Priorities List. IBWA requests that, assuming a rule establishing a standard of quality for arsenic for bottled water is proposed by September 30, 2004 (the end of FY2003), that FDA place finalization of this standard on the A list for CFSAN's Program Priorities for 2005. Specifically, FDA is urged to adopt an arsenic standard of quality of 10 ppb for bottled water, with an effective date as early as possible. In addition, FDA should also maintain the same annual monitoring frequency and the process for compliance determinations that are currently in place for bottled water under 21 CFR§128.80(g)(2). IBWA has already lowered the Association's Model Code standard of quality for arsenic to 10 ppb, with an effective date of January 1, 2002.
2. Reducing Food Security Risks. IBWA has noted and appreciates that a major focus of FDA's 2004 CFSAN Program Priorities was assuring food safety and security. IBWA urges FDA to continue working with the food industry in developing methods for reducing security risks within each food category. IBWA requests that FDA place cooperative development of strategies for reduction of security risks for bottled water on the A list for CFSAN's Program Priorities for 2005. This cooperative and collaborative approach will permit a productive exchange of information and provide the foundation for specific industry actions to address the variety of security risks associated with the production of bottled water. It is the shared goal of FDA and the bottled water industry to reduce the security risks and to continue to provide safe, quality bottled water to consumers. Because of the complexity of the regulated food industry, this voluntary approach will afford flexibility for both FDA and the various impacted food categories in designing methods for reducing security risks and encouraging communications and innovation. This will assist in mitigating the burdens on industry and commerce.
3. Revised Monitoring Requirements for Nine Compounds: In FDA's *Federal Register* notice dated August 6, 1998, it was stated that FDA intended to release guidance on compliance monitoring for the nine contaminants, including the four (4) synthetic organic chemicals (SOCs). As such guidance has not yet been issued, IBWA prepared and submitted (May 11, 2003) for FDA review, proposed guidance for this monitoring. IBWA recommended that if there are no detects for the four SOCs during the initial three-year compliance period, that source water be tested annually and that finished product be tested once every three years. IBWA requests that FDA include amending 21 C.F.R. §165.110, to reflect a revised monitoring schedule for the nine contaminants, on the B list for CFSAN's Program Priorities for 2005.

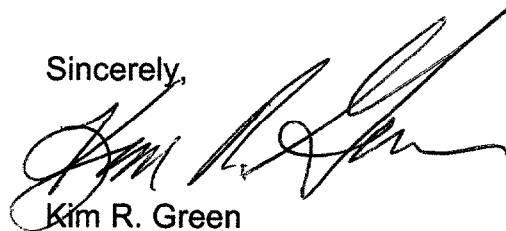
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Thank you in advance for your consideration of IBWA's comments. If you have any questions about IBWA's comments, please do not hesitate to contact me at (703) 647-4614.

Sincerely,

A handwritten signature in black ink, appearing to read 'Kim R. Green', written in a cursive style.

Kim R. Green

Vice President of Research, Science &  
Technical Affairs